

CORRELATION OF PLASMA FIBRINOGEN WITH BLOOD PRESSURE, BMI, LIPID PROFILE AND GLYCEMIC STATUS IN TYPE II D MSuresh Harsoor¹, Akshaya Kinagi², Ananta³**HOW TO CITE THIS ARTICLE:**

Suresh Harsoor, Akshaya Kinagi, Ananta. "Correlation of Plasma Fibrinogen with Blood Pressure, BMI, Lipid Profile and Glycemic Status in Type II D M". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 68, December 08; Page: 14615-14627, DOI: 10.14260/jemds/2014/3963

ABSTRACT: BACKGROUND: Diabetes is the most common metabolic disorder all over the world³. The incidence of diabetes is showing an alarming rise in developing countries, particularly in India. Type 2 diabetes is the most prevalent form in India and constitutes more than 95% of the cases.⁹ During the past decade, the potential role of haemostatic factors particularly fibrinogen in various disorders and their complication has gained considerable interest. Plasma fibrinogen is an important marker in type 2 Diabetes, but its correlation with smoking, age, sex, hypertension, obesity, family history lipids, has not been evaluated in large studies. In view of paucity of data from Indian studies, we attempt to correlate plasma fibrinogen with blood pressure, BMI, lipid profile and glycemic status in type 2 diabetes mellitus. **METHODS:** A total of 100, known and newly detected type-2 diabetic patients with and without associated hypertension of more than 40 years of age belonging to both sexes were included. All these patients were registered cases in Basaveshwar Teaching & General Hospital, Gulbarga as outpatients and in-patients. Type-2 diabetic patients associated with myocardial infarction, stroke, chronic inflammatory diseases, tuberculosis, malignancy, secondary hypertension and pregnancy were excluded from this study. After a detailed clinical examination, the following investigations were done: For diabetes mellitus: Random blood sugar, fasting blood sugar, post-prandial blood sugar and glycosylated haemoglobin (ERBA Kit). Renal profile: Blood urea and serum creatinine. Serum lipids: Cholesterol, triglyceride (TG), high density lipoprotein (HDL) and low density lipoprotein (LDL) by commercially available kits (ERBA Kit). Routine urine examination: Sugar and albumin. Estimation of plasma fibrinogen: The plasma fibrinogen was estimated by thrombin-clotting method by using FIBROQUANT KIT [Tulip Diagnostics (P) Ltd.]. **OBJECTIVES:** To know the fibrinogen levels in patients of type-2 diabetes mellitus. To correlate plasma fibrinogen levels in patients of type-2 diabetes mellitus with blood pressure, body mass index, lipid profile and glycemic status. **RESULTS AND CONCLUSIONS:** Fibrinogen, the immediate precursor of fibrin was frequently elevated in type-2 diabetic patients and this elevation was associated with poor glycemic control as evidenced by increased glycosylated haemoglobin levels. But not all type-2 diabetic patients had higher levels of plasma fibrinogen. The patients who had normal range of plasma fibrinogen levels had normal glycosylated haemoglobin. The other parameters which correlated with plasma fibrinogen levels were age, smoking, family history, and body mass index. But alcohol consumption was inversely correlated to plasma fibrinogen level. The females had higher fibrinogen levels compared to males and also those who had hypertension showed higher plasma fibrinogen levels than normotensives, but this difference was not significant. Though various studies asserted that serum lipids and duration of diabetes has no correlation with plasma fibrinogen level, the present study showed positive correlation between serum cholesterol level, LDL level and triglyceride level with plasma fibrinogen levels. There was inverse relation with HDL level and duration of diabetes. In view of the fact that the present study comprised of a small

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group of patients, further studies with more number of patients may be required to evaluate our observations.

KEYWORDS: Diabetes; plasma fibrinogen; glycemic status; BMI; lipid profile, hypertension.

INTRODUCTION: During the past decade, the potential role of haemostatic factors particularly fibrinogen in various disorders and their complication has gained considerable interest.¹ It has now been established through several cross-sectional prospective epidemiological studies that plasma fibrinogen concentration is a strong and an independent cardiovascular risk factor along with other risk factors such as smoking, age, sex, hypertension, obesity, family history and lipids.^{2,3,4} etc. The plasma fibrinogen predicts cardiovascular events in general population, diabetics and non-diabetic patients with clinical vascular disease.¹

Epidemiologic studies have long demonstrated the strong and often independent direct correlation between high plasma fibrinogen levels and cardiovascular disease, but the mechanisms by which fibrinogen would act is still unclear⁴. The interest in relationship between diabetes mellitus and fibrinogenemia has grown, as an increase in fibrinogen levels may be one of the mechanisms by which diabetes exerts its effect on cardiovascular risk.^{5,6}

Elevation of fibrinogen levels and impaired fibrinolysis are more common in diabetic patients than in non-diabetic patients, although discordant results have been reported. Increased plasma fibrinogen concentrations were with those of other acute phase reactants in the emerging view of sub-clinical inflammation as a characteristic of and possibly a risk factor for type-2 diabetes mellitus.⁷

Microalbuminuria also represents a sensitive marker of cardiovascular disease, which is associated with hyper-fibrinogenemia in type-2 diabetes mellitus.⁸

The plasma fibrinogen levels were found to be high in type-2 diabetic subjects with hypertension than those without hypertension⁹. But others found no difference between hypertensive and normotensive diabetic patients¹⁰. The fibrinogen levels were also found to be high in obese patients with BMI > 30 Kg/m². Some authors found that BMI was independently related to fibrinogen levels¹ and decreases with weight reduction but others found no correlation of fibrinogen with changes in BMI.^{11,12}

In total, the plasma fibrinogen levels are increased in type-2 diabetes mellitus, thus suggesting that hyper-fibrinogenemia could contribute to the excess cardiovascular morbidity and mortality in this disease. However, the mechanisms leading to increased fibrinogen concentration in type-2 diabetes mellitus remains unknown.

AIMS OF THE STUDY:

1. To know the fibrinogen levels in patients of type-2 diabetes mellitus.
2. To correlate plasma fibrinogen levels in patients of type-2 diabetes mellitus with blood pressure, body mass index, lipid profile and glycemic status.

MATERIALS AND METHODS: This study included 100 cases of type-2 diabetes mellitus who attended the out-patient department and admitted as in-patients at Basaveshwar Teaching and General Hospital Gulbarga.

A total of 100, known and newly detected type-2 diabetic patients with and without associated hypertension of more than 40 years of age belonging to both sexes were included. All

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these patients were registered cases in Basaveshwar Teaching & General Hospital, Gulbarga as outpatients and in-patients. Type-2 diabetic patients associated with myocardial infarction, stroke, chronic inflammatory diseases, tuberculosis, malignancy, secondary hypertension and pregnancy were excluded from this study carried out.

After a detailed clinical examination, the following investigations were done:

- a) For diabetes mellitus: Random blood sugar, fasting blood sugar, post-prandial blood sugar and glycosylated haemoglobin (ERBA Kit).
- b) Renal profile: Blood urea and serum creatinine.
- c) Serum lipids: Cholesterol, triglyceride (TG), high density lipoprotein (HDL) and low density lipoprotein (LDL) by commercially available kits (ERBA Kit).
- d) Routine urine examination: Sugar and albumin.
- e) Estimation of plasma fibrinogen.

OBSERVATIONS AND RESULTS:

Age (years)	Sex		Total No. of patients	Percentage
	Male	Female		
40-49	15	10	25	25.00
50-59	28	11	39	39.00
60-69	10	12	22	22.00
70-79	9	3	12	12.00
>80	1	1	2	2.00
Total	63	37	100	100.00

Table 1: Distribution of types 2 DM patients according to age and sex

The Table-1 shows maximum number of type-2 diabetic patients in the age group of 50-59 years (39 patients, 39.9%) and the least patients were in the group of 80 years (2 patients, 2%). The youngest patient was 40 years and the eldest patient was 82 years old. The mean age of the patient was 6.3 years. The sex distribution among the patient groups showed male preponderance with respect to each age group and as a whole. Actually the study contains 63 numbers of males and 37 numbers of females.

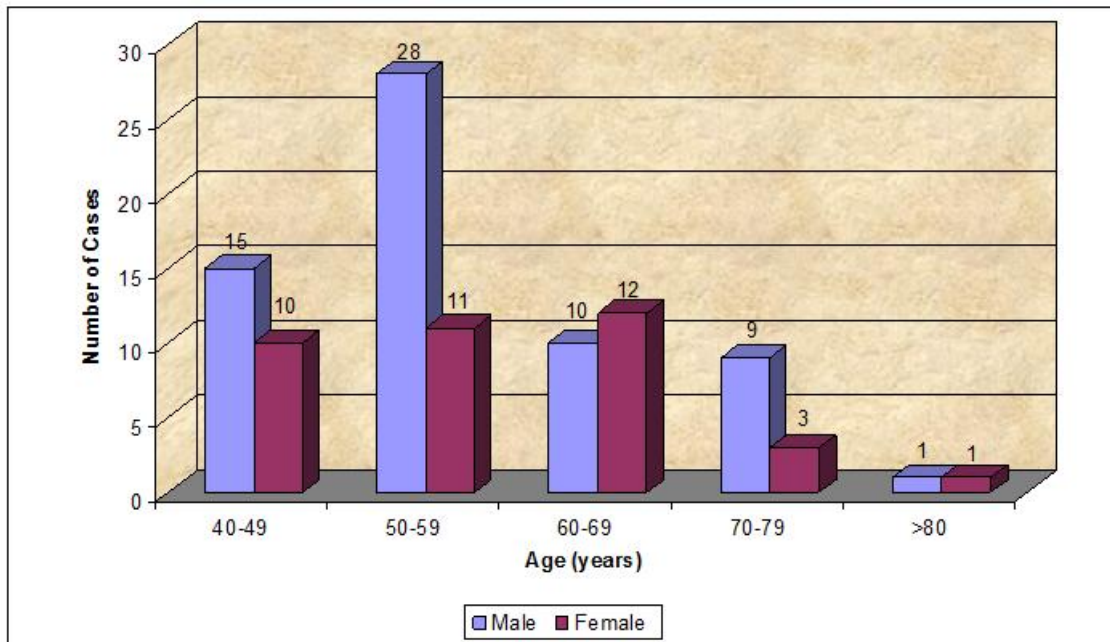


Figure 1: Distribution of type-2 DM patients according to Age and Sex

Family history	Fibrinogen level Mean \pm SD (g/L)	Number of patients	Percentage
Positive family history	7.45 \pm 1.10	26	26.00
Negative family history	5.12 \pm 1.98	74	74.00

Table 2: Correlation of fibrinogen levels with family history of HTN/DM

The above table shows relatively higher mean plasma fibrinogen levels in patients with family history of hypertension and diabetes compared to those without family history (7.45 \pm 1.10 versus 5.12 \pm 1.98g/L). Out of 100 patients, only 26 patients had family history of either hypertension or diabetes or both.

On applying Z test, the value was found to be $z=7.397$ ($p<0.001$), which was highly significant. So, type-2 diabetic patients with family history of diabetes or hypertension or both had significantly higher mean plasma fibrinogen level compared to those without family history.

Duration (years)	Fibrinogen level Mean \pm SD (g/L)	Number of patients	Percentage
< 1 years	6.09 \pm 1.36	18	18.00
1-4	5.80 \pm 1.71	33	33.00
5-9	6.41 \pm 1.57	19	19.00
10-14	6.62 \pm 1.40	15	15.00
15-19	6.15 \pm 1.27	12	12.00
>20	3.57 \pm 0.35	3	3.00

Table 3: Correlation of fibrinogen levels with duration of DM

The above table shows duration of diabetes ranging from less than one year to twenty five years. On applying correlation test, the correlation coefficient was found to be $r=0.7$ and $t=9.76$ ($p<0.01$, highly significant). So there was a negative correlation between fibrinogen level and duration of diabetes.

Blood pressure	Fibrinogen level Mean \pm SD (g/L)	Number of patients	Percentage
Hypertension	6.26 \pm 1.67	62	62.00
Normotensive	5.75 \pm 1.40	38	38.00

Table 4: Correlation of Fibrinogen level with Blood Pressure

The above table shows, higher fibrinogen levels in type-2 diabetic patients with hypertension compared to normotensives. The hypertensive patients had 6.26 \pm 1.67 g/L fibrinogen levels compared to patients without hypertension 5.75 \pm 1.40 g/L. Out of 100 type-2 diabetic patients 62 had hypertension, 32 were normotensive patients. On applying z test, the value was found to be 1.642 ($p>0M5$), which was insignificant. So even though hypertensive patients had higher fibrinogen level compared to normotensive patient, the difference was insignificant.

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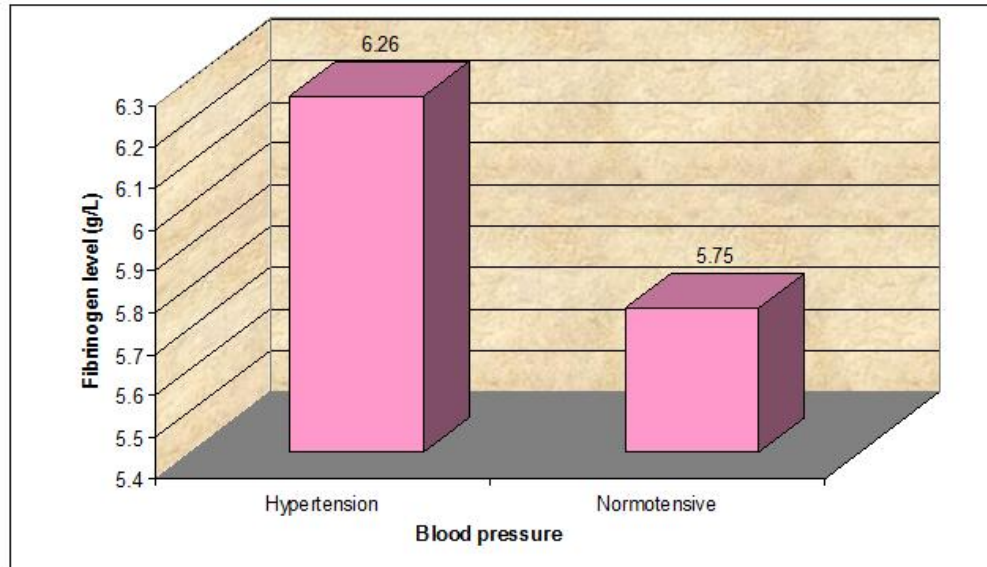


Figure 1 A: Correlation of Fibrinogen Level with blood pressure

BMI (kg/m ²)	Fibrinogen level Mean \pm SD (g/L)	Number of patients	Percentage
<20	5.65 \pm 0.65	4	4.00
20-26	5.60 \pm 1.56	52	52.00
27-30	5.53 \pm 1.74	26	26.00
>30	7.00 \pm 1.15	18	18.00

Table 5: Correlation of Fibrinogen Level with Body Mass Index

In the above table, the body mass index of patient's ranges from 17.58 to 38.26 Kg/m² and fibrinogen level ranges from 5.65 \pm 0.65 to 7.00 \pm 1.15 g/L. The patients with BMI more than 30 Kg/m² had significantly higher plasma fibrinogen level (7.00 \pm 1.15) compared to those with less body mass index. On applying correlation test, the correlation coefficient was found to be $r=0.68$ and $t=9.714$ ($p<0.001$), which was highly significant. So there was a positive correlation between BMI and plasma fibrinogen level.

Table 6: Correlation of Fibrinogen Level with Lipid Profile:

Cholesterol level (mg/dL)	Fibrinogen level Mean \pm SD (g/L)	Number of patients	Percentage
100-149	6.43 \pm 2.01	9	9.00

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150-199	5.76±1.43	64	64.00
200-249	6.58±1.52	24	24.00
250-299	7.47±1.82	3	3.00

Table-6A: Correlation of Fibrinogen Level with Serum Cholesterol

In the above table, 9 patients had serum cholesterol level between 100-149 mg/dL and mean plasma fibrinogen level of 6.43 ± 2.01 and 64 patients had serum cholesterol level between 150-199 mg/dL and mean plasma fibrinogen level of 5.76 ± 1.43 . 24 patients had serum cholesterol level between 250-249 mg/dL and mean plasma fibrinogen level of 6.58 ± 1.52 and remaining 3 patients had serum cholesterol level between 250-299 mg/dL with mean plasma level of 7.41 ± 1.82 .

On applying correlation test, the correlation coefficient was found to be $r=0.75$ and $t=11.21$ ($p<0.001$), which was significant. So there was a significant positive correlation between plasma cholesterol level and plasma fibrinogen level

Triglyceride level (mg/dL)	Fibrinogen level Mean \pm SD (g/L)	Number of patients	Percentage
100-149	3.19 ± 0.15	5	5.00
150-199	3.80 ± 0.19	9	9.00
200-249	4.63 ± 0.49	18	18.00
250-299	6.12 ± 0.46	35	35.00
300-349	7.35 ± 0.26	24	24.00
350-399	8.43 ± 0.16	8	8.00
>400	9.80 ± 0.85	2	2.00

Table 6B: Correlation of Fibrinogen Level with Serum Triglyceride Level

This table shows a linear increase in plasma fibrinogen level as serum triglyceride level increases. The patients who had serum triglyceride level between 100-149 mg/dL had plasma fibrinogen level about 3.19 ± 0.15 g/L and those with serum triglyceride level more than 400 mg/dL had 9.80 ± 0.85 g/L plasma fibrinogen level.

On applying correlation test, the correlation coefficient was found to be $r=0.96$ and $t=34.16$ ($p<0.001$), which was highly significant. So there was a significant positive correlation between serum triglyceride level and plasma fibrinogen level.

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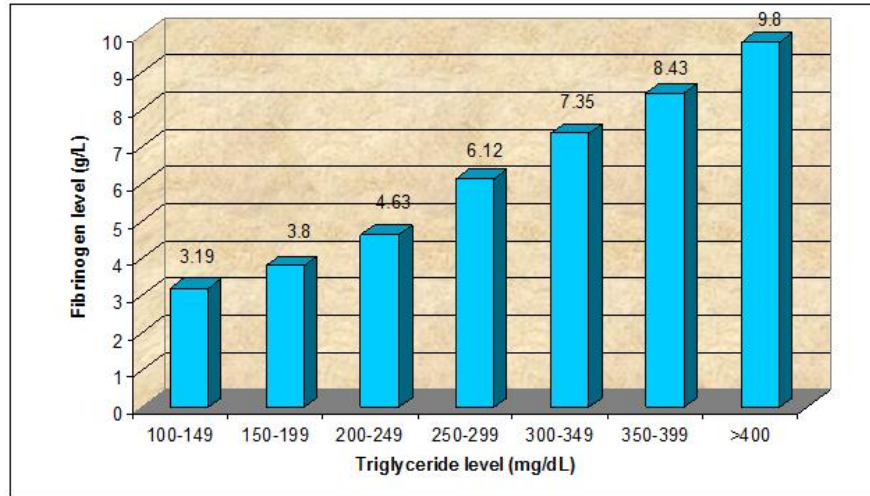


Figure 2: Correlation of Fibrinogen Level with Serum Triglyceride Level

HDL level (mg/dL)	Fibrinogen level Mean \pm SD (g/L)	Number of patients	Percentage
30-34	6.63 \pm 1.72	19	19.00
35-39	6.29 \pm 1.50	36	36.00
40-44	6.14 \pm 1.36	30	30.00
45-49	4.33 \pm 1.10	12	12.00
>50	6.03 \pm 1.19	3	3.00

Table 6C: Correlation of Fibrinogen Level with Serum HDL Level

In the above table 19 patients with HDL level 30-34 mg/dL had plasma fibrinogen level of 6.63 \pm 1.72 g/L. Thirty six patients with HDL level '3539 mg/dL had plasma fibrinogen level of 6.29 \pm 1.50 g/L. Thirty patients with HDL level 40-44 mg/dL had plasma fibrinogen level of 6.14 \pm 1.36 g/L. Twelve patients with HDL level 45-49 mg/dL had plasma fibrinogen level 4.39 \pm 1.10 g/L and lastly 3 patients with HDL level more than 50 mg/dL had plasma fibrinogen level of 6.03 \pm 1.19 g/L.

On applying correlation test, the correlation coefficient was found to be $r=-0.65$ and $t=8.425$ ($p<0.001$), which was significant. So there was a significant negative correlation between serum HDL and plasma fibrinogen level.

LDL level (mg/dL)	Fibrinogen level Mean \pm SD (g/L)	Number of patients	Percentage
<50	6.31 \pm 1.99	5	5.00
50-99	5.73 \pm 1.47	37	37.00
100-149	6.10 \pm 1.55	54	54.00
150-199	5.89 \pm 2.05	4	4.00

Table 6D: Correlation of Fibrinogen Level with Serum LDL Level

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In the above table, 5 patients with LDL level less than 50 mg/dL had plasma fibrinogen level 6.31 ± 1.99 g/L. Thirty seven patients with LDL level between 50-99, had plasma fibrinogen level of 5.73 ± 1.47 g/L. Fifty four patients with LDL level between 100-149 mg/dL had plasma fibrinogen level of 6.10 ± 1.55 and lastly 4 patients with LDL level between 150-199 mg/dL had plasma fibrinogen level of 5.89 ± 2.05 .

On applying correlation test, the correlation coefficient was found to be $r=0.53$ and $t=6.23$ ($p<0.01$) which was significant. So there was a positive correlation between serum LDL level and plasma fibrinogen level.

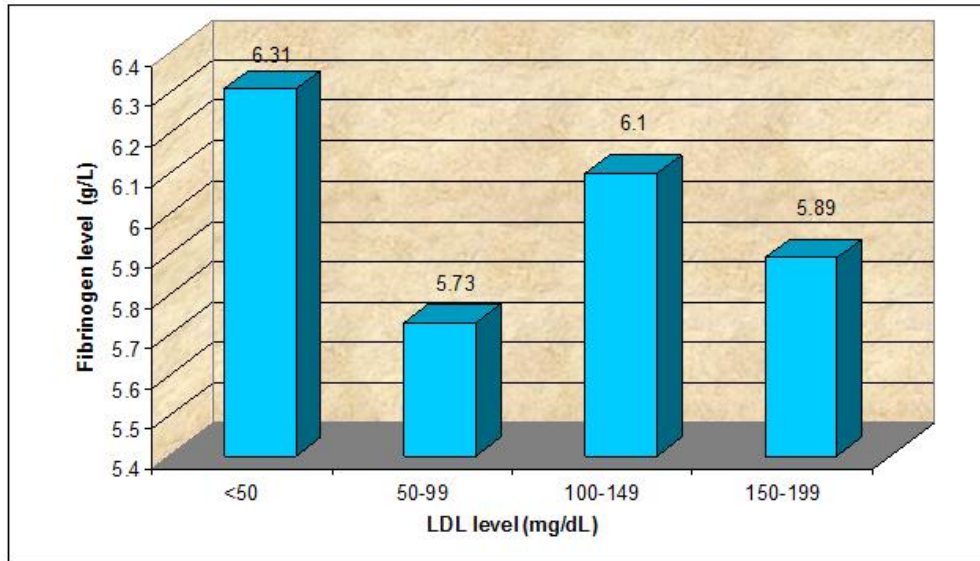


Figure 3: Correlation of Fibrinogen Level with Serum LDL Level

Glycosylated Haemoglobin	Fibrinogen level Mean \pm SD (g/L)	Number of patients	Percentage
6.0-6.9	3.55 ± 0.34	13	13.00
7.0-7.9	4.96 ± 0.52	29	29.00
8.0-8.9	7.08 ± 0.59	48	48.00
9.0-9.9	8.43 ± 0.16	8	8.00
>10	9.80 ± 0.85	2	2.00

Table 7: Correlation of Fibrinogen Level with Glycosylated Haemoglobin (Gly Hb)

In the above table, the patients who had glycosylated haemoglobin ranging from 6.0-6.9%, had mean plasma fibrinogen value. of 3.55 ± 0.34 g/L. 29 patients, who had glycosylated haemoglobin ranging from 7.0 to 7.9%, had mean plasma fibrinogen value of 4.96 ± 0.52 g/L.

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48 patients who had glycosylated haemoglobin ranging from 8.0 to 8.9%, who had mean plasma fibrinogen value of 7.08 ± 0.59 g/L. 8 patients who had glycosylated haemoglobin ranging from 9.00 to 9.9%, had mean plasma fibrinogen value of 8.43 ± 0.16 g/L and remaining 2 patients had glycosylated haemoglobin more than 10% and they had mean plasma fibrinogen value of 9.80 ± 0.85 g/L.

On applying correlation test, the correlation coefficient was found to be $r=0.96$ and $t=33.56$ ($p<0.001$), which was highly significant. So there was a positive correlation between glycosylated haemoglobin and plasma fibrinogen level. As glycosylated haemoglobin level increases, plasma fibrinogen level also increases.

DISCUSSION: Fibrinogen concentrations vary widely among populations and it increases with aging. The levels are consistently higher in women than in men and rise after menopause. Smoking is the most important life-style that is found to correlate with fibrinogen. People with diabetes and hypertension have elevated fibrinogen levels, as do sedentary and obese individuals. Alcohol intake and estrogen replacement therapies are associated with lower fibrinogen levels. Most other CVD risk factors are correlated positively with fibrinogen.¹³

The fibrinogen was found to correlate with serum triglyceride levels and inverse association was found with HDL cholesterol and physical activity.¹⁴

The highlights of the present study are as Follows:

The age group of the patients ranged from 40-85 years and maximum number of patients were seen in 50-59 years age group. The sex distribution showed male preponderance.

The results showed age-related increase in mean plasma fibrinogen levels among type-2 diabetic patients. In female patients compared to male patients, plasma fibrinogen levels were higher but this increase was not statistically significant. Higher mean plasma fibrinogen levels were noted in patients with family history of diabetes and/or hypertension, CAD compared to the patients with no such family history [7.45 ± 1.10 versus 5.12 ± 1.98 g/L ($p<0.001$)]

In Bruno G et al study, in men, plasma fibrinogen level increased with age but in women plasma fibrinogen level increased almost by 0.4 g/L only between premenopausal and postmenopausal ages, but no significant linear trend was detected.¹⁵ The other studies in which age was positively correlated with fibrinogen level were Temelkova et al study,¹⁶ Lam TH et al study,¹⁷ Om P.Ganda study,¹⁸ Bruno G et al study¹⁹ and Christophe Tribonilloy et al. study.²⁰

The duration of diabetes among patients ranged from less than one year to 25 years and maximum number of patients were between 1 to 4 years. There was negative correlation between plasma fibrinogen and duration of diabetes. This study showed higher fibrinogen levels in smokers than non-smokers among male patients. This difference was statistically significant (6.90 ± 1.01 versus 4.32 ± 1.15 ; $p<0.001$).

The male patients with history of alcohol consumption had lower fibrinogen levels compared to non-alcoholics. But the difference was statistically significant (5.37 ± 1.37 versus 6.12 ± 1.58 ; $p<0.05$).

In our study, higher plasma fibrinogen levels were noted in type-2 diabetic patients with hypertension compared to normotensives. Out of 100 patients, 62 patients had hypertension.

The difference in plasma fibrinogen levels among hypertensive and normotensive patients was statistically insignificant (6.26 ± 1.67 versus 5.75 ± 1.40 ; $p>0.05$).

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The body mass index (BMI) was correlated in each patient and was correlated with plasma fibrinogen levels and found that there was positive correlation between BMI and plasma fibrinogen level. All the patients with BMI more than 30 Kg/m², had significantly higher plasma fibrinogen levels, compared to others.

In the present study, serum lipids were measured in each patient such as serum cholesterol, triglyceride, HDL and LDL and their correlation with plasma fibrinogen level was ascertained. The positive correlation was found between cholesterol level, LDL level and triglyceride levels and negative correlation between HDL level and plasma fibrinogen level.

Glycosylated haemoglobin showed a linear correlation with plasma fibrinogen level in this study. Mean plasma fibrinogen value increased as HbA1C value increased.

CONCLUSION: Diabetic patients exhibit increased concentration of plasma pro-anti coagulant proteins and diminished concentrations of functionally attenuated anti-thrombotic factors leading to hypercoagulable status, possibly explaining in part, the high cardiovascular event rate in these patients.

Fibrinogen, the immediate precursor of fibrin was frequently elevated in type-2 diabetic patients and this elevation was associated with poor glycemic control as evidenced by increased glycosylated haemoglobin levels. But not all type-2 diabetic patients had higher levels of plasma fibrinogen. The patients who had normal range of plasma fibrinogen levels had normal glycosylated haemoglobin.

The other parameters which correlated with plasma fibrinogen levels were age, smoking, family history, and body mass index. But alcohol consumption was inversely correlated to plasma fibrinogen level. The females had higher fibrinogen levels compared to males and also those who had hypertension showed higher plasma fibrinogen levels than normotensives, but this difference was not significant.

Though various studies asserted that serum lipids and duration of diabetes has no correlation with plasma fibrinogen level, the present study showed positive correlation between serum cholesterol level, LDL level and triglyceride level with plasma fibrinogen levels. There was inverse relation with HDL level and duration of diabetes.

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Date of Submission: 07/11/2014.
Date of Peer Review: 13/11/2014.
Date of Acceptance: 03/12/2014.
Date of Publishing: 05/12/2014.